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TITLE: Addressing the Health Concerns of VA Women with Sexual Trauma

PRINCIPAL INVESTIGATOR: Caron Zlotnick, PhD

CONTRACTING ORGANIZATION:
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14. ABSTRACT
The purpose of our proposed research is to develop and assess a computer-delivered intervention (Safety and Health Experiences Program; SHE) that will provide a screening and brief behavior intervention for women Veterans with any lifetime sexual trauma. The completed scope of work to date includes the completion of informant interviews and the open trial, ongoing safety monitoring of all studies, and the start of the randomized control study. Major findings to date are that the open trial demonstrated feasibility of recruitment of target population, acceptability of the intervention (i.e., completion rate of intervention was high (95%) and acceptance ratings were adequate), and the acceptability of study procedures was good (i.e., retention rate at 4 months was 90%).

15. SUBJECT TERMS
Safety and Health Experiences Program; SHE
Sexual Trauma (ST)

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1. INTRODUCTION:

Our proposed research will develop and assess a computer-delivered intervention (Safety and Health Experiences Program; SHE) that will provide a screening and brief behavior intervention for women veterans with any lifetime ST. More specifically, the intervention, SHE, will address interrelated health concerns for women veterans with ST (i.e., alcohol misuse, IPV, and PTSD). We plan to develop our proposed computer-based intervention with input from our team of investigators as well as information gained in focus groups and informant interviews with women veterans with ST. We will conduct a small trial of SHE with 20 women veterans with lifetime ST to examine if the intervention is acceptable to our population. Finally, we will recruit a sample of 150 women veterans who screen positive for any lifetime ST and have at least one risk factor (i.e., IPV, PTSD, or heavy drinking) and randomize them to the SHE intervention or to a screen and referral (SR) condition. We will examine whether SHE compared to SR will result in decreases in the number of risks and increase resource and treatment utilization at the 2- and 4-month follow-up.

2. KEYWORDS:

Safety and Health Experiences Program; SHE
Sexual Trauma (ST)
Intimate Partner Violence (IPV)
Posttraumatic Stress Disorder (PTSD)
Screen and referral (SR)
Open trial (OT)
Randomized control trial (RCT)
Data Safety Monitory Board (DSMB)

3. ACCOMPLISHMENTS:

Major Activities:

1. Completion of informant interviews
2. Conducted the open trial
3. Conducting the randomized control study
4. Ongoing safety monitoring of all studies

Specific Objectives:

1) Organized and conducted informant interviews (N=34)
2) Refined the intervention, SHE based on feedback from informant interviews
3) Recruitment of participants for OT (N=20)
4) Baseline and follow-up assessments and delivery of SHE for OT
5) SHE and study modifications
6) Began data analysis of OT
7) DMSB meetings held and maintenance of research regulatory compliance

Significant Results:

Major findings to date include the following: Thirty-five women completed the screening survey. Of the 20 eligible women (58%) enrolled in the open trial phase (OT), no-one dropped out or withdrew before enrollment. (See Consort Table 1). Of the 20 women enrolled in

the open trial, 6 women (30%) identified themselves as Hispanic. 6 women (30%) identified as Black or African American, 2 women (10%) identified as Bi-Racial or Multi-Ethnic, 8 women (40%) identified as Caucasian, 1 woman (5%) identified as Asian, and 3 women (15%) identified as Other. Sixteen (80%) reported sexual trauma before the age of 14, and of those 8 (50%) reported rape. 12 (60%) reported rape after the age of 14. The average age for participants enrolled in the OT was 41 years old (range = 25-63). 19 (95%) had been granted a service disability, 8 (42%) for mental health. Overall, of the 20 women enrolled in the OT, 20 women (100%) completed a baseline assessment and 19 (95%) completed their assigned intervention modules. 19 women (95%) completed the follow up assessment 2 months later and 18 (90%) the 4-month assessment. Mean average ratings on the Client Satisfaction Questionnaire Revised (CSQ-R) for the alcohol intervention module was 23 (SD=5.24), for the IPV module was 24.11 (SD=5.9), and for the PTSD was 27.75 (SD=5.24). At the exit interviews, most participants reported favorable responses to the intervention. Critical comments were directed at the baseline assessments and participants were apt to confuse the baseline assessments with the intervention. We reworded the instructions to the Client Satisfaction Questionnaire Revised to increase the likelihood that women in the RCT assess the intervention and not include the baseline assessments in their responses to the CSQ-R. Participants' average score on the 7-item Satisfaction with the CIAS Software measure that taps satisfaction on items on likeability, ease of use, level of interest, and respectfulness using a 1 – 5 Likert scale (1 = low, and 5 = high) was for the alcohol intervention of 28.6 (SD=5.0), for the intimate partner violence intervention was 28.8 (SD=4.37) and for the PTSD intervention was 31.4 (SD=4.33). To date, there have been 5-serious (not expected/unrelated) adverse reports that have been reported to the DSMB and the IRB. To date, for the OT there have been 2 non-serious adverse events; one expected/related and one not expected/unrelated.

We have started recruitment for the RCT. To date, we have recruited 23 women for the RCT (see Consort Table 2). In the RCT, to date, there has been 1 non-serious expected/related adverse report that was reported to the DSMB and IRB. To date there have been 2 SAEs (not expected, not related) that were reported to the DSMB and IRB. We have met our projected recruitment milestones for the year. To date, we have recruited 77 eligible study participants.

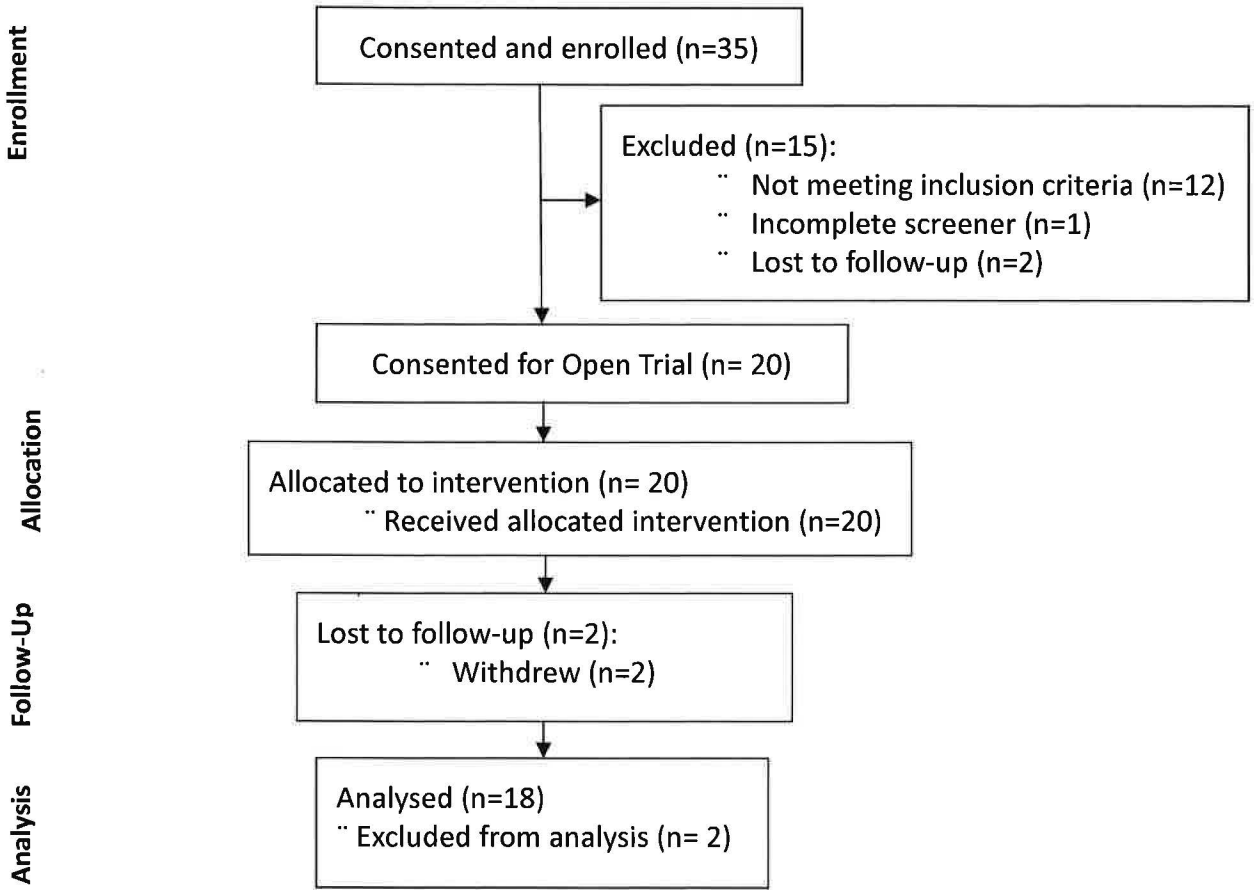
There has been a delay in the data analysis for the open trial, which should have been completed in month 11 (The project start date was 8/16). This delay is due to the following factors: The Texas Central VA Healthcare System requires study data to be reviewed for identifying information before it can be released. Also, our full-time research assistant resigned in August 2017 and spent much of her time documenting her duties and preparing for the transition. Hence, there was a delay in the last few participants' OT data (i.e., the 4-month follow-up assessment data) being downloaded into SPSS, and the data set being released. We are currently cleaning and checking the SPSS files for the 4-month follow-up assessments.

Conclusions to date:

The OT demonstrated feasibility of recruitment of target population, the acceptability of the SHE intervention (i.e., completion rate of intervention was high and the acceptance ratings of treatment were adequate), and the acceptance of study procedures was good (i.e., retention rate at 4 months was 90%).

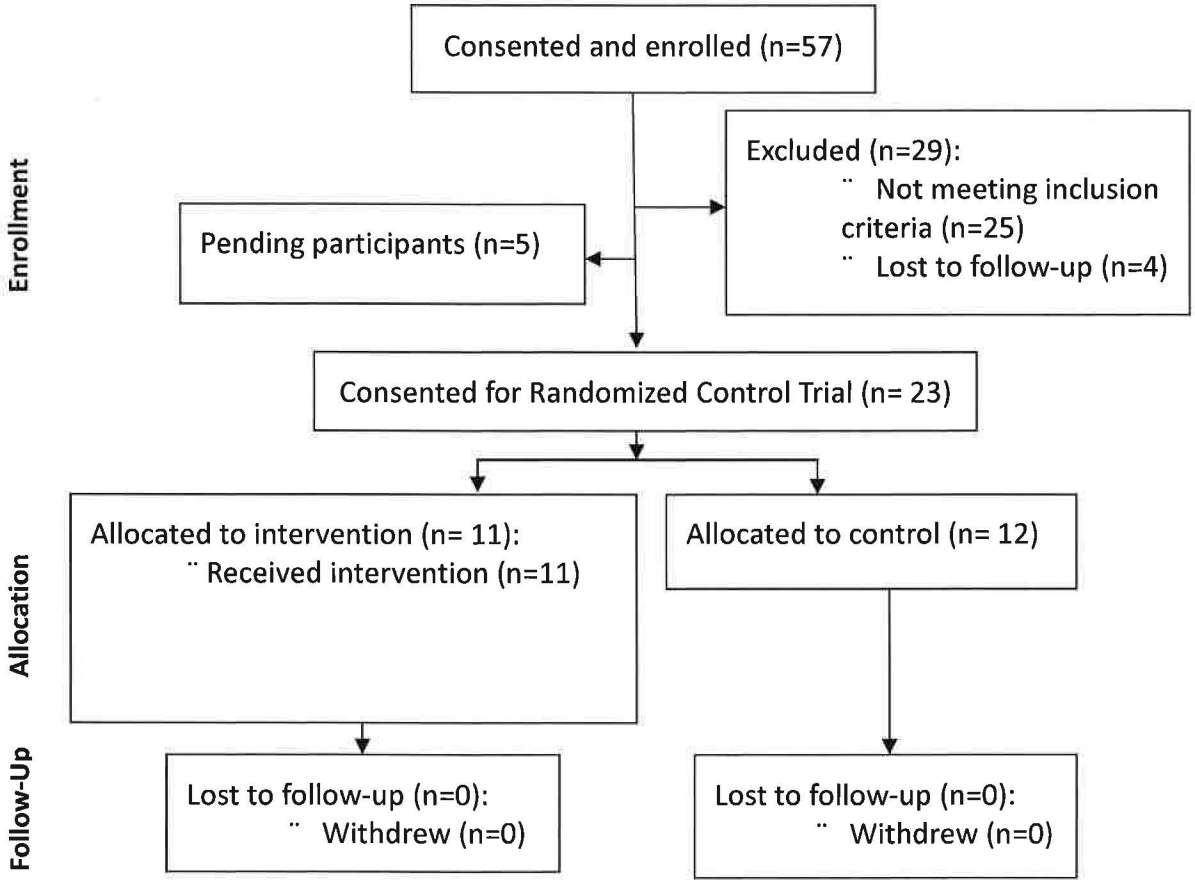
Consort Table 1

Addressing the Health Concerns of VA Women with Sexual Trauma
(Open Trial)



Consort Table 2

Addressing the Health Concerns of VA Women with Sexual Trauma
(Randomized Trial)



4. IMPACT:

Nothing to Report.

5. CHANGE/PROBLEMS:

No changes to the protocol since last annual meeting

Actual or anticipated problems or delays and actions or plans to resolve them:

Our full-time research assistant resigned in August of this year. We have part time research assistants familiar with the study to conduct follow-up assessments, associated research related tasks, and limited recruitment. This has and will obviously cause delays in the study. Fortunately, we have hired a research assistant who will begin mid-December who is familiar with the study.

6. PRODUCTS:

Nothing to Report.

7. PARTICIPANTS & OTHER COLLABORATING ORGNIZATIONS:

Name:	*Caron Zlotnick*
Project Role:	*Principle Investigator*
Researcher Identifier (e.g. ORCID ID):	none
Nearest person month worked:	*3*
Contribution to Project:	Dr. Zlotnick has been responsible for the overall conduct of the project.
Funding Support:	

Name:	*Suzannah Creech*
Project Role:	*Co-I/Site PI*
Researcher Identifier (e.g. ORCID ID):	0000-0002-6582-1673
Nearest person month worked:	*1*
Contribution to Project:	Oversees project tasks and personnel at the Central Texas site of the project.
Funding Support:	

Name:	*Jeisa Jones*
Project Role:	*Research Technician*
Researcher Identifier (e.g. ORCID ID):	none
Nearest person month worked:	*11*
Contribution to Project:	Ms. Jones is the full time research technician on the study.
Funding Support:	

Name:	*Lindsay Orchowski*
Project Role:	*Co-I*
Researcher Identifier (e.g. ORCID ID):	none
Nearest person month worked:	*1*
Contribution to Project:	Provides expertise in sexual trauma and motivationally-based alcohol use interventions, and contributes to presentations.

Funding Support:	

There have been changes in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period.

Caron Zlotnick (PI)

The following grants have ended:

Treatment of PTSD in Residents of Battered Women's Shelters
R01MH095767-01 (PI: Johnson) 08/01/2012 - 06/30/2017 1.2CM
National Institutes of Health
Role: Co-I

Computer-based Intervention for Victimized Perinatal Women with Mental Illness
R21HD077358 (PI: Zlotnick) 09/01/2014 - 06/31/2017 0.6 CM
National Institutes of Health

Suzannah Creech (Site PI)

The following grant has started:

National Implementation of VA Rollout of Strength at Home
4500002368 (PI: Taft) 07/01/17-06/30/18 1.2 Calendar
Bob Woodruff Foundation

The following grant has ended:

Extension of the Implementation of VA Rollout of Strength at Home
(Taft: PI) 9/1/16-9/1/17 1.2 Calendar
Bob Woodruff Foundation

Lindsay Orchowski (Co-I)

The following grants has started:
Integrated Prevention of HIV risk and Intimate Partner Violence among Adolescents in South Africa
R34MH113484 (Kuo: PI) 8/1/17 - 5/31/2020 (1.10 CM)
National Institutes of Health
Role: Co-I

Golfo Tzilos (Co-I)

The following grants has started::
Translation of an Evidenced-Based Violence Intervention for Adolescents in Primary Care.
Centers for Disease Control and Prevention Injury Prevention and Control Research and State and Community Based Programs (PI, Cunningham). 08/01/17 – 07/31/19 (.60 Cal Mos).
Role Co-I

Christopher Kahler (Co-I)

The following grants have started:

The Substance Use Research Core provides services for studies assessing and intervening on substance use and its impact on the full continuum HIV prevention and care.
NIAID P30AI042853 (Cu-Uvin) 07/01/17 – 06/30/18 (0.5 Calenda)r
Role: Core co-Director

Working Memory Training Combined with Repetitive Transcranial Magnetic Stimulation In Smokers
NIDA 1R21DA042989-01A1 (Lechner, Philip) 07/15/17 – 07/30/19 0.1 Calendar
Role: co-Investigator

Tracie M Shea (Co-I)
The following grant has started:
Pilot Testing of Theta-Burst Neuromodulation for Chronic PTSD
Department of Veterans Affairs I01RX002032 (Philip) 4/1/16-3/30/18 (0.60 Calendar)
Role: Co-Investigator

8. SPECIAL REPORTING REQUIREMENTS:
Nothing to Report.

9. APPENDICES:
Nothing to Report.

Addressing the Health Concerns of VA Women with Sexual Trauma

PT130611 Psychological Health and Traumatic Brain Injury Research Project
W81XWH-14-1-0368

PI: Caron Zlotnick **Org: Women & Infants Hospital** **Award Amount: $1,022,633**

Study Aims and Approach

1. Development Aims are to develop a computer-based screening and brief intervention program that targets interrelated health risks (i.e. alcohol misuse, IPV, and PTSD) for women veterans with lifetime ST using information gathered from informant interviews (N=34). An open pilot trial (N=20) with women veterans with ST who seek VA primary care and who have at least one ST-related risk will help to refine the intervention.
2. Trial Aims are to conduct a randomized controlled pilot trial in a sample of 150 women veterans with ST who are heavy drinkers, screen positive for PTSD, and/or screen positive for IPV to demonstrate the feasibility of the proposed recruitment methods, design, and delivery of the intervention. We will examine evidence for the hypotheses that the intervention, relative to the control group, at the 2- and 4-month follow-up, will reduce the number of risks (i.e., heavy drinking (4+ drinks), screen positive for PTSD, or screen positive for IPV) and will increase resource and treatment utilization.

•Accomplishments: Completed the informant interviews (N=34) and refined the intervention based on feedback from informant interviews. Completed the open trial. Open trial (N=20) results demonstrated the feasibility of recruitment of target population, the acceptability of the intervention (i.e., completion rate of intervention was high and treatment acceptance ratings were adequate) and the acceptability of study procedures (i.e., retention rate at 4 months was 90%). The randomized control study has begun.

Timeline and Cost

Activities	Yr 1	Yr 2	Yr 3
Informant Interviews			
Focus Groups			
Open Trial			
Randomized Pilot Trial			
Estimated Budget ($1.2 M)	**$364K**	**$342K**	**$316K**

Updated: (October 16, 2017)

Year 1 :
- ❑ Develop the computer–based assessments and intervention based on input from informant interviews,
- ❑ Obtain all regulatory approvals,
- ❑ Conduct open trial
- ❑ Begin randomized control study

• **Year 2**
- ❑ Continue randomized control study
- ❑ Continuation of research regulatory compliance

Year 3
- ❑ Continue randomized control study
- ❑ Prepare data for scientific manuscripts, resource sharing, and grant submissions

Comments/Challenges/Issues/Concerns
None.

Budget Expenditure to Date
Projected Expenditure:$4214K
Actual Expenditure: $341,570